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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-19-0980; Docket No. CDC-2019-0011]

Proposed Data Collection Submitted for Public Comment and

Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC),

Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled National Environmental Assessment Reporting System (NEARS) to collect data from foodborne illness outbreak environmental assessments routinely conducted by local, state, territorial, or tribal food safety programs during outbreak investigations.

DATES: CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2019-0011 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office,
   Centers for Disease Control and Prevention, 1600 Clifton Road,
   N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency
name and Docket Number. CDC will post, without change, all
relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

## SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information

they conduct or sponsor. In addition, the PRA also requires

Federal agencies to provide a 60-day notice in the <u>Federal</u>

<u>Register</u> concerning each proposed collection of information,
including each new proposed collection, each proposed extension
of existing collection of information, and each reinstatement of
previously approved information collection before submitting the
collection to the OMB for approval. To comply with this
requirement, we are publishing this notice of a proposed data
collection as described below.

The OMB is particularly interested in comments that will help:

- 1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- 2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- 3. Enhance the quality, utility, and clarity of the information to be collected; and
- 4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of

information technology, e.g., permitting electronic submissions of responses.

5. Assess information collection costs.

## Proposed Project

National Environmental Assessment Reporting System (NEARS) (OMB Control No. 0920-0980, Exp. 8/31/2019) - Revision - National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

## Background and Brief Description

Environmental Assessment Reporting System (NEARS) (0920-0980) to collect data from foodborne illness outbreak environmental assessments routinely conducted by local, state, territorial, or tribal food safety programs during outbreak investigations.

Prior to the development of NEARS, environmental assessment data were not collected at the national level. The data reported through this surveillance system provides timely information on the causes of outbreaks, including environmental factors associated with outbreaks, and are essential to environmental public health regulators' efforts to respond more effectively to outbreaks and prevent future, similar outbreaks. This surveillance system was specifically designed to link to CDC's National Outbreak Reporting System (NORS), a disease (e.g. enteric diseases transmitted by food) outbreak surveillance

system. NEARS was developed by the Environmental Health
Specialists Network (EHS-Net), a collaborative network of CDC,
the U.S. Food and Drug Administration (FDA), the U.S. Department
of Agriculture (USDA), and nine state food safety programs
(California, Connecticut, Georgia, Iowa, New York, Minnesota,
Oregon, Rhode Island, and Tennessee). The network consists of
environmental health specialists (EHSs), epidemiologists, and
laboratorians. EHS-Net developed a standardized protocol for
identifying, reporting, and analyzing data relevant to foodborne
illness outbreak environmental assessments.

While conducting environmental assessments during outbreak investigations is routine for food safety program officials, reporting information from the environmental assessments to CDC is not routine. Local, state, federal, territorial, and tribal food safety programs are the primary respondents for this data collection. One official from each participating program will report environmental assessment data on outbreaks. These programs are typically located in public health or agriculture agencies. In the U.S., there are approximately 3,000 such agencies. Currently, 31 state and local health departments are registered to report data on outbreaks to NEARS. Based on our experience over the past five years, we expect up to 10 additional local and state public health departments to register to report outbreak data to NEARS over the next three years.

It is not possible to determine exactly how many outbreaks will occur in the future, nor where they will occur. Based on past trends, it is likely that up to 300 foodborne illness outbreaks may be reported annually to NEARS from up to 41 entities for the duration of the next PRA clearance. Only programs in the jurisdictions in which these outbreaks occur would report to NEARS. Thus, not every program of the approximate 3,000 programs will respond every year. Assuming each outbreak occurs in a different jurisdiction, there will be one respondent per outbreak.

The activities associated with NEARS that require a burden estimate consist of training, observing, data recording, and data reporting events. The first activity is the training for the food safety program personnel participating in NEARS. These staff will be encouraged to attend a Skype Meeting (i.e., webinar) training session conducted by CDC staff. Training burden is based on the maximum expected participation from the reporting entities which could be up to 10 additional local and state health departments. We estimate the burden of this training to be a maximum of two hours. Respondents will only be required to take this training one time. Assuming a maximum participation of up to 10 programs and about five staff being trained at each participating program, the total estimated burden associated with this training is 100 hours.

Food safety program personnel participating in NEARS will also be encouraged to complete CDC's Environmental Assessment

Training Series (EATS). This eCourse provides training to staff on how to use a systems approach in foodborne illness outbreak environmental assessments. We estimate the burden of this training to be a maximum of 10 hours. Respondents will only have to take this training one time. Assuming a maximum participation of up to 10 programs and approximately five staff being trained at each program, the estimated burden associated with this training is 500 hours.

Data reporting activities for NEARS will be done once for each establishment involved in the outbreak. Information collection activities for NEARS consist of the following: NEARS data reporting and NEARS manager interview. For each outbreak, the respondent (one official from each participating program) will spend around 30 minutes recording environmental assessment data on pen and paper. Assuming a maximum of 300 outbreaks, the estimated annual burden is 150 hours for recording observations.

The manager interview will be conducted at each establishment associated with an outbreak and data is initially recorded using pen and paper. The respondents for this activity are the retail food managers of the outbreak establishments.

Most outbreaks are associated with only one establishment; however, some are associated with multiple establishments. We

estimate that a maximum of four manager interviews will be conducted per outbreak. Each interview and data reporting will take about 20 minutes. Assuming a maximum of 300 outbreaks, the estimated annual burden is 400 hours. Web-based data entry for both data recording and the manager interview will be combined. Data entry into the NEARS system is expected to take approximately 40 minutes for the combined activities, for a total of 200 burden hours. The total estimated annual burden for this information collection is 1,350 hours.

Estimated Annualized Burden Hours

Type of	Form Name	Number of	Number of	Average	Total
Respondent		Respondent	Responses	Burden	Burde
S		S	per	per	n (in
			Responden	Respons	hours
			t	e (in	)
				hours)	
Food	NEARS Food	50	1	2	100
safety	Safety				
program	Program				
personnel	Training				
	NEARS e-	50	1	10	500
	Learning				
	(screenshots				
	)				
	NEARS Data	300	1	30/60	150
	Recording				
	(paper form)				
	NEARS Data	300	1	40/60	200
	reporting				
	and				
	manager's				
	interview				
	(web entry)				
Retail	NEARS	1200	1	20/60	400
food	Manager				
personnel	Interview				
Total					1,350

## Jeffrey M. Zirger,

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